

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

GALDERMA LABORATORIES, L.P. and)	
NESTLÉ SKIN HEALTH S.A.)	
)	
Plaintiffs,)	
)	
v.)	
)	C.A. No. _____
AMNEAL PHARMACEUTICALS, LLC and)	
AMNEAL PHARMACEUTICALS PVT.)	
LTD.,)	
)	
Defendants.)	
)	

COMPLAINT

Plaintiffs Galderma Laboratories, L.P. (“Galderma”) and Nestlé Skin Health S.A. (“NSH”) (collectively, “Plaintiffs”), for their Complaint against Defendants Amneal Pharmaceuticals, LLC (“Amneal Pharma”) and Amneal Pharmaceuticals Pvt. Ltd. (“Amneal India”) (collectively, “Amneal” or “Defendants”), hereby allege as follows:

THE PARTIES

1. Plaintiff Galderma is a privately held partnership registered in the State of Texas, having a principal place of business at 14501 North Freeway, Fort Worth, Texas 76177.
2. Plaintiff NSH is a “société anonyme” organized and existing under the laws of Switzerland, having a principal place of business at Avenue Gratta Paille 2, 1018 Lausanne, Switzerland.
3. Upon information and belief, Defendant Amneal Pharma is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 85 Adams Avenue, Hauppauge, NY 11788.

4. Upon information and belief, Defendant Amneal India, formerly known as Amneal Pharmaceuticals Co. (I) Pvt. Ltd., is an Indian corporation and a wholly-owned subsidiary and agent of Defendant Amneal Pharma, having a principal place of business at 882/1-871, Village: Rajoda, Near Hotel Kankavati, Taluka: Bavla, District: Ahmedabad-382220, Gujarat, India.

5. Plaintiffs Galderma and NSH and Defendants Amneal Pharma and Amneal India are presently parties to a related appeal pending before the Federal Circuit, *Galderma Laboratories, L.P. et al. v. Amneal Pharmaceuticals LLC et al.*, C.A. No. 2019-1021 (Fed. Cir.) (“the *Amneal II* Appeal”).

6. The *Amneal II* Appeal stems from an action in this district, *Galderma Laboratories, L.P. et al. v. Amneal Pharmaceuticals LLC et al.*, No. 16-cv-207-LPS (D. Del.) (“the *Amneal II* Action”). In the *Amneal II* Action, the Court entered judgment that Amneal had infringed the asserted claims of five valid U.S. Patents, including U.S. Patent Nos. 8,603,506 (“the Ashley ’506 patent”) and 9,241,946 (“the Ashley ’946 patent”) (collectively, “the Related Ashley patents”), through Amneal’s submission to the U.S. Food and Drug Administration (“FDA”) and maintenance of Abbreviated New Drug Application (“ANDA”) No. 203278 (“Amneal’s ANDA”) for a 40 mg doxycycline oral capsule product proposed for the indication of “treatment of only inflammatory lesions (papules and pustules) of rosacea in adult patients” (“Amneal’s ANDA Product”), for which Amneal seeks approval prior to the expiration of the Related Ashley patents and other patents listed in the Orange Book for ORACEA[®] Capsules. *See generally* D.I. 289-290, C.A. No. 16-207-LPS.

7. As set forth below, Plaintiffs now bring the instant action regarding Amneal’s infringement of United States Patent No. 10,058,564 (“the Ashley ’564 patent”) (attached as

Exhibit A), arising from the same infringing acts by Amneal as asserted in the *Amneal II* Action previously litigated before this Court and presently on appeal.

NATURE OF THE ACTION

8. This is a civil action for infringement of the Ashley '564 patent. This action arises under the Patent Laws of the United States, 35 U.S.C. §§ 100 *et seq.*, as well as the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02.

JURISDICTION AND VENUE

9. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

10. Venue is proper in this district pursuant to 28 U.S.C. §§ 1391(b)-(d) and 1400(b).

11. This Court has personal jurisdiction over Amneal Pharma because, *inter alia*, it is a Delaware company.

12. This Court has personal jurisdiction over Defendants Amneal Pharma and Amneal India by virtue of the fact that, *inter alia*, Defendants have committed, aided, abetted, contributed to, and/or participated in the commission of a tortious act of patent infringement under 35 U.S.C. § 271(e)(2) that has led and/or will lead to foreseeable harm and injury to Plaintiffs, including in the State of Delaware. Upon information and belief, Defendants intend to engage in the commercial manufacture, use, and/or sale under Amneal's ANDA of Amneal's ANDA Product before the expiration of the Ashley '564 patent, throughout the United States, including in the State of Delaware.

13. Upon information and belief, Amneal Pharma is the agent for Amneal India for purposes of making regulatory submissions to the United States Food and Drug Administration ("FDA"), including Amneal's ANDA No. 203278 at issue in this litigation.

14. Upon information and belief, Amneal Pharma and Amneal India have acted in concert with respect to the preparation and filing of ANDA No. 203278 for Amneal's ANDA Product and in preparation to sell the ANDA Product in the United States, including in the State of Delaware.

15. Upon information and belief, following approval of ANDA No. 203278 by the FDA, Amneal Pharma and Amneal India will act in concert to commercialize Amneal's ANDA Product throughout the United States, including in the State of Delaware.

16. Amneal's infringing activities with respect to its filing of ANDA No. 203278 and intent to commercialize Amneal's ANDA Product have led and/or will lead to foreseeable harm and injury to Plaintiffs, including in the state of Delaware.

17. This Court also has personal jurisdiction over Amneal Pharma and Amneal India by virtue of the fact that, upon information and belief, *inter alia*, Amneal Pharma and Amneal India have availed themselves of the rights and benefits of Delaware law, and have engaged in systematic and continuous contacts with the State of Delaware.

18. Upon information and belief, Amneal Pharma and Amneal India, directly or through their subsidiaries, affiliates or agents, develop, formulate, manufacture, market, import and sell pharmaceutical products, including branded drug products and generic drug products, throughout the United States, including in the State of Delaware.

19. This Court also has personal jurisdiction over Defendants Amneal Pharma and Amneal India because they have previously submitted to the jurisdiction of this Court and have affirmatively availed themselves of the legal protections of the State of Delaware, having asserted counterclaims against Galderma in this jurisdiction in the *Amneal II* Action and in a related patent infringement litigation previously before this Court regarding the same ANDA No.

203278. *See* D.I. 11, C.A. No. 16-207-LPS; *Galderma Labs. Inc. v. Amneal Pharm., LLC*, No. 11-cv-1106-LPS (D. Del.). Further, Amneal Pharma and Amneal India have asserted counterclaims in this jurisdiction in other matters. *See, e.g., Sanofi v. Amneal Pharm. LLC*, No. 14-cv-875-RGA (D. Del.); *Meda Pharm. Inc. v. Amneal Pharm. LLC*, No. 15-cv-617-GMS (D. Del.); *UCB Inc. v. Amneal Pharm. LLC*, No. 13-cv-1208-LPS (D. Del.); *Novartis Pharm. Corp. v. Amneal Pharm. LLC*, No. 15-cv-1025-RGA (D. Del.); *AstraZeneca LP v. Amneal Pharm. LLC*, No. 15-cv-1056-RGA (D. Del.); *AstraZeneca Pharm. LP v. Amneal Pharm. LLC*, No. 15-cv-1139-GMS (D. Del.); *AbbVie Inc. v. Amneal Pharm. LLC*, No. 12-cv-235-SLR (D. Del.); *Forest Labs. Inc. v. Amneal Pharm. LLC*, No. 13-cv-1737-SLR (D. Del.); *Forest Labs. LLC v. Amneal Pharm. LLC*, No. 15-cv-430-SLR (D. Del.); *Prometheus Labs. Inc. v. Amneal Pharm. LLC*, No. 14-cv-968-LPS (D. Del.); *Teva Pharm. USA Inc. v. Amneal Pharm. LLC*, No. 15-cv-124-GMS (D. Del.); *Hospira Inc. v. Amneal Pharm. LLC*, No. 15-cv-697-RGA (D. Del.); *Forest Labs. LLC v. Amneal Pharm. LLC*, No. 15-cv-756-LPS (D. Del.); *AstraZeneca LP v. Sigmapharm Labs., LLC*, No. 15-cv-1000-RGA (D. Del.).

THE PATENTS-IN-SUIT

20. Plaintiff Galderma holds New Drug Application No. 50-805 on ORACEA[®] (doxycycline, USP) 40 mg Capsules, and is the exclusive distributor of ORACEA[®] Capsules in the United States.

21. On August 28, 2018, the Ashley '564 patent, entitled "Methods of Treating Acne" was duly and legally issued to Galderma. The Ashley '564 patent is from the same patent family as the Related Ashley patents, which also name Robert A. Ashley as the inventor.

22. NSH is the current owner of the Ashley '564 patent.

23. The Ashley '564 patent is listed in the FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* ("Orange Book") for ORACEA[®] Capsules.

AMNEAL'S ANDA, NOTICE LETTERS, AND THE *AMNEAL II* ACTION

24. Upon information and belief, Amneal Pharma, with the collaboration or assistance of Amneal India, submitted ANDA No. 203278 to the FDA under § 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)), including a certification under § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act ("Paragraph IV Certification"), seeking approval to engage in the commercial manufacture, use, sale, or offer for sale within the United States, or importation into the United States, of Amneal's ANDA Product prior to the expiration of the patents listed in the Orange Book for ORACEA[®] Capsules, which, at that time included, among other things, the Related Ashley patents.

25. Upon information and belief, Amneal has stated that the proposed ANDA Product will be marketed for the currently approved indication for ORACEA[®] Capsules.

26. On February 17, 2016, Amneal sent a letter to Galderma and NSH, signed by Candis Edwards, Senior Vice President – Regulatory Affairs, representing that Amneal had filed a Paragraph IV Certification in ANDA No. 203278 with respect to the Related Ashley patents and other Orange Book listed patents for ORACEA[®] Capsules, and that Amneal is seeking approval of its ANDA Product under ANDA No. 203278 prior to the expiration of those patents ("the February 17, 2016 Notice Letter").

27. Amneal's infringement of the Related Ashley patents and other Orange Book listed patents for ORACEA[®] Capsules was litigated in the *Amneal II* Action. A five-day bench trial was held in the *Amneal II* Action in February 2018.

28. On August 27, 2018, the Court issued its judgment in the *Amneal II* Action, finding that Amneal infringed the asserted claims of five valid U.S. Patents, including the Related Ashley patents. *See* D.I. 289-290, C.A. No. 16-207-LPS.

29. The Ashley '564 patent was listed in the Orange Book for ORACEA® Capsules on September 25, 2018. Upon information and belief, Amneal continues to seek approval of its NDA Product prior to the expiration of the Orange Book listed patents for ORACEA® Capsules, despite the new issuance and listing of the Ashley '564 patent.

AMNEAL'S INFRINGEMENT OF THE ASHLEY '564 PATENT

30. Plaintiffs re-allege paragraphs 1-29 as if fully set forth herein.

31. By seeking approval of their ANDA No. 203278 to engage in the commercial manufacture, use, sale, or offer for sale within the United States, or importation into the United States, of Amneal's ANDA Product prior to the expiration of the Ashley '564 patent, Amneal has infringed that patent under 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents.

32. Defendants Amneal Pharma and Amneal India are jointly and severally liable for infringement of the Ashley '564 patent under 35 U.S.C. § 271(e)(2)(A). Upon information and belief, Amneal Pharma and Amneal India actively and knowingly caused to be submitted, assisted with, participated in, contributed to, or directed the submission of ANDA No. 203278 seeking to engage in the commercial manufacture, use, sale, or offer for sale within the United States, or importation into the United States, of Amneal's ANDA Product prior to the expiration of the Ashley '564 patent.

33. Moreover, if Amneal manufactures, uses, offers for sale, or imports into the United States any of Amneal's ANDA Product, or induces or contributes to any such conduct,

prior to the expiration of the Ashley '564 patent, including any applicable exclusivities or extensions, Amneal would infringe the one or more claims of the Ashley '564 patent under 35 U.S.C. § 271(a), (b) and/or (c), either literally or under the doctrine of equivalents.

34. Plaintiffs are entitled to relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of ANDA No. 203278 be a date that is not earlier than the expiration date of the Ashley '564 patent, or any later expiration of any patent term extension or exclusivity for the Ashley '564 patent to which Plaintiffs become entitled.

35. Plaintiffs will be irreparably harmed by Amneal's infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

PRAYER FOR RELIEF

Plaintiffs request that the Court grant the following relief:

A. An Order adjudging and decreeing that Defendants Amneal Pharma and Amneal India have infringed the Ashley '564 patent by submitting ANDA No. 203278 to the FDA and seeking FDA approval of ANDA No. 203278 prior to the expiration of the Ashley '564 patent;

B. An Order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of Amneal's ANDA No. 203278 will not be earlier than the expiration date of the Ashley '564 patent, or any later expiration of any patent term extension or exclusivity for the Ashley '564 patent to which Plaintiffs are or become entitled;

C. An Order permanently enjoining Defendants Amneal Pharma and Amneal India, their directors, officers, agents, attorneys, affiliates, divisions, successors and employees, and those acting in privity or concert with them, from manufacturing, using, offering to sell, selling, marketing, distributing, or importing Amneal's ANDA Product identified in this Complaint, or

any product that infringes the Ashley '564 patent, prior to the expiration of the Ashley '564 patent, including any extensions to which Plaintiffs are or become entitled;

D. That Plaintiffs be awarded monetary relief to the extent Defendants commercially manufacture, use, offer for sale, or sell within the United States, or import into the United States any product that infringes or induces or contributes to the infringement of the Ashley '564 patent, within the United States prior to the expiration of the aforementioned patent, including any later expiration of any patent term extension or exclusivity for the Ashley '564 patent to which Plaintiffs are or will become entitled, and that any such monetary relief be awarded to Plaintiffs with prejudgment interest; and

E. Such other and further relief as the Court may deem just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

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March 1, 2019